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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/632,532      | 08/01/2003  | Enrique Saldivar     | RM 0001P            | 2660             |

7590 12/13/2006  
FUESS & DAVIDENAS  
17258 Amarillo Road  
Ramona, CA 92065



EXAMINER

TURK, NEIL N

ART UNIT PAPER NUMBER

1743

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/632,532

Applicant(s)

SALDIVAR ET AL.

Examiner

Neil Turk

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 10-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/1/04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, drawn to an apparatus for measuring blood platelet contractility, classified in class 422, subclass 73.
- II. Claims 10-16, drawn to a system for automatically measuring platelet contractility in a plurality of samples, classified in class 73, subclass 1.59.
- III. Claim 17, drawn to a method of measuring blood platelet contractility, classified in class 436, subclass 69.
- IV. Claims 18-21, drawn to a method for automatically measuring a plurality of samples to determine strength of platelet contractility, classified in class 436, subclass 43.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together, they have different designs in that invention I requires, among other elements, a flexible membrane within a spherical rigid chamber, while invention II requires a pump and microprocessor system with a computer a readout and memory system connected, and

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have different effects in that invention I relates pressure changes that alter the diameter of the thin flexible membrane and invention II has the effect of determining the direction of flow in the pump and activates the pump fluid pressure for a target pressure to be reached.

Inventions III and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process of invention III can be practiced by hand, and the apparatus of invention I does not require the adhesive applied to flexible membrane.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together, invention I is drawn to an apparatus with a flexible membrane within a spherical rigid chamber such that pressure changes are measured as a result of the membrane being altered, and invention II is drawn to a pressure calibration method by use of valves and a microprocessor carrying out various iterative steps.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together, invention III is drawn to

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a method of measuring the degree of contractility in a pressure transducer after adding a sample to the outside of the flexible membrane, and invention IV is drawn to a pressure calibration method.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together, invention II is drawn to a system for converting signals so as to determine the direction of flow in the pump and activating the pump fluid pressure within the system, and invention IV is drawn to a pressure calibrating method.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together, invention II is drawn to a system for converting signals to determine the direction of flow in the pump and activating the pump fluid pressure within the system, and invention III is drawn to a method for measuring the degree of contractility in a pressure transducer after sample has been added to the outside of an adhesive-applied flexible membrane.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

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During a telephone conversation with Bill Fuess on November 29<sup>th</sup>, 2006 a provisional election was made without traverse to prosecute the invention of I, claims 1-9. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the etching and the void spaces must be shown or the feature(s) canceled from the claim(s). It is unclear how such "etching" as shown constitutes a boundary in which the operator "snaps" the clay plug into. The drawing have many "void spaces" and without being specifically shown, it is unclear where such specific void spaces are in the design. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

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replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "3" has been used to designate both the rigid reservoir and in the lower half of figure 5, character "3" is directed to a different part other than the rigid reservoir as shown above it. Further reference characters "1", "2", and "4" all designate two different parts between the upper figure in A and the lower figure in B of figure 5.

Additionally, in figure 5, A designates "3", the rigid chamber, at the same position of "6" in B, which is designated as etching. This is similarly found between A and B with the respective pairs of "2" & "5" and "4" & "7".

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Figure 5 and its respective A and B portions as drawn appear to be identical drawings, with the difference being the portion that extends out of the opening at the upper surface of the circle designated with outer radius,  $r_o$ . As will be discussed below, the description of the figure does not alleviate this issue and those discussed above, such that it does not define all of the characters and the description does not adequately describe each embodiment in and of itself.

Additionally, the void spaces

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Appropriate correction is required.



### ***Specification***

The disclosure is objected to because of the following informalities: The description of Figure 5 and its respective parts A and B is unclear for the reasons stated above. The description of figure 5 fails to describe the two separate designs such that incomplete descriptions are provided for both A and B of figure 5.

Appropriate correction is required.

### ***Claim Objections***

**Claim 1** is objected to because of the following informalities: the word "membrane" should appear after "flexible" in line 18 of claim 1 so as to maintain proper antecedent basis with the previously recited "flexible membrane chamber" of claim 1. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1-9** are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the specification on pages 11, 29, and 30 discloses that the flexible membrane is coated with a suitable adhesive in order to avoid slippage of the clots over the membrane surface.

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Independent claims 1, 3, and 7 do not contain this necessary limitation, and the subsequent dependent claims contain such a deficiency because of their dependence to the respective independent claims.

**Claim 5** recites the limitation "the plug" in line 13. There is insufficient antecedent basis for this limitation in the claim.

***Allowable Subject Matter***

**Claims 1-9** would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach or fairly suggest an apparatus for measuring blood platelet contractility in which a spherical rigid chamber has a smaller, flexible membrane placed concentrically within the rigid chamber so as to create a void space between the rigid chamber and the flexible membrane. The closest prior art of record, Carr Jr. (USPN 4,986,964) discloses a clot retractometer in which a rigid chamber is connected to a coupling arm, which connects to a pressure transducer for detecting pressure changes as the sample exerts pressure changes on the upper plate of the rigid chamber.


### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's field of endeavor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Turk whose telephone number is 571-272-8914. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700

|                                   |                                       |   |             |
|-----------------------------------|---------------------------------------|---|-------------|
| <b>Notice of References Cited</b> | Application/Control No.<br>10/632,532 | Applicant(s)/Patent Under<br>Reexamination<br>SALDIVAR ET AL. |             |
|                                   | Examiner<br>Neil Turk                 | Art Unit<br>1743  | Page 1 of 1 |

**U.S. PATENT DOCUMENTS**

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Name                 | Classification |
|---|---|--|-----------------|----------------------|----------------|
| * | A | US-4,986,964                                     | 01-1991         | Carr et al.          | 422/73         |
| * | B | US-5,455,009                                     | 10-1995         | Vogler et al.        | 422/102        |
| * | C | US-5,925,569                                     | 07-1999         | Gorog et al.         | 436/69         |
| * | D | US-5,441,892                                     | 08-1995         | Baugh, Robert F.     | 436/69         |
| * | E | US-6,613,573                                     | 09-2003         | Cohen, Eli           | 436/69         |
| * | F | US-6,573,104                                     | 06-2003         | Carr et al.          | 436/69         |
| * | G | US-5,293,772                                     | 03-1994         | Carr, Jr., Marcus E. | 73/64.41       |
|   | H | US-  |                 |                      |                |
|   | I | US-  |                 |                      |                |
|   | J | US-  |                 |                      |                |
|   | K | US-  |                 |                      |                |
|   | L | US-  |                 |                      |                |
|   | M | US-  |                 |                      |                |

**FOREIGN PATENT DOCUMENTS**

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Country | Name | Classification |
|---|---|--|-----------------|---------|------|----------------|
|   | N |  |                 |         |      |                |
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|   | R |  |                 |         |      |                |
|   | S |  |                 |         |      |                |
|   | T |  |                 |         |      |                |

**NON-PATENT DOCUMENTS**

| * |   | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) |
|---|---|---|
|   | U |   |
|   | V |   |
|   | W |   |
|   | X |   |

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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